

## Return to Screening PDSA and Clinical Study - June 23, 2021 - Q and A with Answers

Question Asked	Answer Given
I was under the impression that the standard will be fulfilled if the 10% increase in screening isn't achieved, but the health system completes the study and PDCA with complete documentation. Is this still correct?	Participation will still qualify if the 10% increase goal is not met as long as there is documentation  that there is continued effort to improve the rate. This includes but is not limited to, assessing your  improvement, and trying multiple interventions in an attempt to close the gap.
Can you please confirm that the links to begin entering screening rates and interventions online have not been shared yet?	Form A (enrollment and baseline form) is now closed (deadline was June 1st). Form B/C should have been emailed to all those who completed enrollment with unique links to their Form B/C for the institution and disease site
Can we still participate if we started interventions July 1?	We need interventions started by June 1st at the latest
We actually saw an increase in screening during the pandemic (I believe because we had 2 new providers join our team). Will this be an issue in participating in this study?	A gap is not required for participation. You may participate if your plan is to try to increase monthly screenings by 10% over your current screening rate.
Are there any requirements for our team? We are very short staffed and would like to keep our team as small as possible for this project	This PDSA and clinical research involves having a QI team, a local PI (for clinical research) and a team that can assess monthly rates and interventions for this study to be successful. Please refer to the PDF that gives detailed information of what is expected of the local QI team
Is any other documentation needed (specific intervention data) or just the 3 forms?	Form A/B/C submitted in Redcap by deadline
Will this be available to meet CoC standards for future years?	This specific project only qualifies for 2021 credit. We will be looking into similar opportunities for future years.
Should we list interventions that were started before June 1st?	Yes- if the intervention was started after March of 2021, please list these interventions and enter the start date
Are we able to edit the data once submitted in forms.	Data can be edited in Form B/C until final submission; please make sure to "save and return later" button at the bottom of REDCap Form B/C to ensure your answers will be properly saved

<p>Would the colorectal screening apply to NAPRC accreditation?</p>	<p>No. Although this is encouraged, the NAPRC standards do not have dedicated standards for screening or Quality Improvement Initiatives.</p>
<p>What do we do if we have not yet received the link with forms B and C via email?</p>	<p>This probably means there was an error with your enrollment (e.x. email misspelled) or the email from redcaps landed in junk/spam folder. The link to Form B/C is sent from redcap@facs.org. Please contact cancer forums if you think you are enrolled but have not received forms</p>
<p>What if you haven't been able to start your intervention on June 1st? We just recently changed EMR's and have had challenges getting the data of which patients are late for screening.</p>	<p>The interventions should be started by June 1st, and it's crucial to be able to figure out the monthly rates of screening from April 2021. If this is not possible, then participation in the clinical research portion may be difficult; but they can participate in the PDSA QI project (i.e. get credit for 7.3, 8.3, but not for 9.1)</p>
<p>Also, what if you didn't list an intervention that you planned on using, on your Form A, but then decided to utilize it?</p>	<p>On Form A, we just asked to list the intervention that was PLANNED for June 1st implementation (not for the whole study period). What will be more important is to list out the interventions that are implemented during each of the months on Form B/C accurately.</p>
<p>What if we don't meet the 10%</p>	<p>Participation will still qualify if the 10% increase goal is not met as long as there is documentation that there is continued effort to improve the rate. This includes but is not limited to, assessing your improvement, and trying multiple interventions in an attempt to close the gap.</p>
<p>In the first talk, it was mentioned that the project will be compliant if you hit the target. Does this mean that if we don't hit the target, that we aren't able to count our work towards the standards? Please clarify.</p>	<p>No. Participation will still qualify if the 10% increase goal is not met as long as there is documentation that there is continued effort to improve the rate. This includes but is not limited to, assessing your improvement, and trying multiple interventions in an attempt to close the gap.</p>
<p>Besides the RedCap Forms, is there any specific documentation that we need to ensure we complete?</p>	<p>No other documents necessary. However, it'll be important to submit Redcap form A/B/C by deadline (December 31st 2021; no extensions). Submissions can start December 1st with november data</p>
<p>We are working on the screening project (not the clinical study) but have not submitted form A. All the preliminary information referenced "retaining documentation". Should we have submitted form A as of now??</p>	<p>If you are just working on the QI/Screening project (and NOT the clinical research study), you do not need to submit any documentation now. Please retain documentation for submission with your Pre-Review Questionnaire at the time of your next site visit.</p>

Would a staging MRI of Breast count as a screening (for known breast CA)	No, that's not a screening test and would be considered diagnostic/surveillance test
Does this count for the entire NAPBC quality requirement, or do we need a study in addition to the PDSA?	NAPBC Standard 6.1 requires two studies each year or one study and a physician specialty specific quality improvement. This project only counts as one of those, so either an additional center specific study or a physician-specialty quality improvement program will also need to be completed.
How can we get a copy of the IRB waiver/ approval and a copy of the protocol?	<a href="https://www.facs.org/quality-programs/cancer/coc/resuming-care">https://www.facs.org/quality-programs/cancer/coc/resuming-care</a>
Please provide a link/ URL to the protocol.	<a href="https://www.facs.org/quality-programs/cancer/coc/resuming-care">https://www.facs.org/quality-programs/cancer/coc/resuming-care</a>
Is it okay to have a month where an intervention is not performed. We have selected two topics and we are planning to role out various interventions every other month.	yes, just keep an eye out on what the monthly rates are during the months when no interventions are performed. If not hitting target (or on pathway to hitting target), we recommend that you implement interventions during those off months
What did you mean by working with some on validating their forms? How do we know if our form is validated?	You would've received an email if you needed data verification. If you have not heard from us, your data does not need verification
There are a lot of the strategies that we already do regardless of this study. Do you want those included in the study, or only the things we do above and beyond our normal operations?	Yes- if the intervention was started after March of 2021, please list these interventions and enter the start date
What if we have to change our baseline volumes? Can we just update forms?	if you need to update Form A, you will need to contact ACS cancer forums. Form B/C can be updated throughout the study period until the final submission in December
What happens if the PI of your study gets a new job during this 6-month period- can you transfer the person responsible?	Please list out the most current PI on Form B/C before submission in December
After submitting my form with the interventions we chose, I went back and corrected an error. (Changed number of interventions from 6 to 5 but didn't change the interventions). Are we supposed to make these changes as we go?	Yes- Form B/C is an activity tracker, and we are not analyzing final data until submission in December, so changes can be made

<p>Some CoC sites have inquired if they can participate in the PDSA/QI now that we are past the June 1st deadline?</p>	<p>Participation will still qualify if the 10% increase goal is not met as long as there is documentation</p> <p>that there is continued effort to improve the rate. This includes but is not limited to, assessing your</p> <p>improvement, and trying multiple interventions in an attempt to close the gap.</p>
<p>What if you find you have more interventions started by/on June 1st than the number stated on the initial application?</p>	<p>No problem- the most accurate information has to be documented in Form B/C regards to # of interventions, and which interventions. The most important part of Form A is "Target goal" calculation, so if those numbers are wrong, you need to contact us to fix those numbers</p>
<p>When should we be filling out the monthly data? June data on July 1st?</p>	<p>We encourage you to fill out the data monthly, hit "save and return later" and come back to it often to review the monthly changes in rates of screening and interventions performed. However, it does not need to be "submitted" until December</p>
<p>I thought after Step one was completed, we were supposed to receive a link and access to RedCap for the completion of Step 2 and Step 3? I have not received it.</p>	<p>Please email us with the disease site you are participating in (i.e. Breast/ Lung/ Colorectal/ Cervical), name of institution, name and email of individual who filled out Form A, and when the form was submitted. If you have the PDF of Form A that was emailed to you when you completed Redcap submission, please attach that as well, and email ACS cancer forums</p>
<p>We have an intervention that started 11/20 but occurs every month. Can we still count/use it?</p>	<p>Yes- if the intervention was started after March of 2021, please list these interventions and enter the start date</p>
<p>Will the site still receive credit for the clinical study even if the 10% increase goal is not met?</p>	<p>Participation will still qualify if the 10% increase goal is not met as long as there is documentation</p> <p>that there is continued effort to improve the rate. This includes but is not limited to, assessing your</p> <p>improvement, and trying multiple interventions in an attempt to close the gap.</p>
<p>Do we have to enter the screening numbers starting with April?</p>	<p>Yes, this serves as our baseline</p>
<p>Our IRB is also asking for additional information</p>	<p>Suggest they submit a detailed question to either coc@facs.org or napbc@facs.org</p>

Can you start intervention planning prior to June 1 for a community educational event, with the event in late June and does that count for starting by June 1?	Yes that is fine, as long as the event is happening in June
A lot of people go on vacation at the end of the year can you complete it early?	Yes, can complete as early as December 1st
Do we submit all screening numbers starting in April even though we did not join the study until the end of May?	Yes, we need April/May rate to serve as our baseline before June interventions
What if you started interventions before June 1st?	Yes- if the intervention was started after March of 2021, please list these interventions and enter the start date
Is it possible to change the study contact?	Please contact us to change the study contact person (from Form A)